

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

IN RE: ETHICON, INC.  
PELVIC REPAIR SYSTEMS  
PRODUCT LIABILITY LITIGATION

MDL No. 2327

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THIS DOCUMENT RELATES TO ALL CASES

**PRETRIAL ORDER # 70**  
(Plaintiff's Motion to Compel Production of Sales Representative Files)

This multidistrict litigation involves surgical mesh products designed, manufactured, marketed, and sold by Defendant, Ethicon, Inc., ("Ethicon") to treat pelvic organ prolapse and stress urinary incontinence. Plaintiffs have moved for an order compelling production of all files created and maintained by Ethicon's sales representatives when marketing Ethicon's pelvic mesh products. (ECF No. 730). Ethicon objects to production of these materials on several grounds; most significantly, that the burdens associated with collecting and supplying the files far outweigh the anticipated relevance and usefulness of the information that they contain. (ECF No. 804). For the reasons that follow, the Court agrees with Ethicon and **DENIES** Plaintiffs' motion to compel.

By way of background, the parties entered into an agreement governing the production of fact sheets by Ethicon. (PTO #41, ECF No. 433). As part of the fact sheets, Ethicon was required to produce the files of all sales representatives involved in Discovery Pool cases. (*Id.*). According to Ethicon, it has produced the files of approximately 129 sales

representatives pursuant to that agreement. The files of the remaining 300 sales representatives have not been supplied because these representatives were not involved in marketing the actual mesh used by the Discovery Pool plaintiffs. Plaintiffs concede that they have received documents from 129 sales representatives, but contend that the productions have been insufficient given that Ethicon has “lost, misplaced, destroyed, or otherwise disposed of the files of bellwether sales representatives.” (ECF No. 730 at 2).

Plaintiffs take the position that they should not be limited to the document production outlined in Pretrial Order #41. They argue that they need a broader cross-section of sales representative files for several reasons. First, these files will establish company policy. According to Plaintiffs, unless they are permitted to look at all of the sales representatives’ files, Ethicon is free to argue that a damaging document found in a Discovery Pool file is nothing more than evidence of unauthorized activity by a “renegade” representative, and is not proof of a company-wide policy or practice. Second, materials in sales representatives’ files are essential to demonstrate a pattern and practice of Ethicon’s misconduct. Plaintiffs assert that Ethicon has a practice of overselling its products; thus, the documents prepared by the representatives will confirm what representations were made to physicians across the country. Third, information collected by sales representatives regarding adverse events, concerns, and complaints is important in determining when Ethicon became aware of various complications associated with its pelvic mesh products. In order to create the time-line, Plaintiffs need access to all of the files. Finally, Plaintiffs believe that the sales representatives’ files will confirm that Ethicon instructed its representatives to train physicians on the use of Ethicon’s pelvic mesh, rather than fund appropriate professional education.

In response, Ethicon argues that Plaintiffs have confused medical device sales representative files with pharmaceutical sales representative files. Ethicon explains through the affidavit of Matthew Henderson, a former Ethicon sales manager, the role of sales representatives in the company's distribution of mesh products. (ECF No. 804-1). Mr. Henderson asserts that medical device representatives are not required to keep detailed records of their contacts with customers for the simple reason that "[m]edical devices are not sold to doctors, but to the facilities at which surgeries take place." (*Id.* at 3). Henderson distinguishes the medical device industry from the pharmaceutical industry, noting that the function of pharmaceutical sales representatives is to create brand awareness with prescribing physicians while medical device sales representatives primarily provide product support to surgical facilities. In light of their function, pharmaceutical sales representatives keep detailed contemporaneous notes of meetings with physicians in order to track the frequency of their interactions and the brand information communicated. To the contrary, detailed call notes are not particularly useful to medical device sales representatives and, therefore, are rarely generated and are not collected or stored in a central repository or database. (*Id.* at 3-4).

In addition, Ethicon indicates that its sales representatives do not create their own marketing or promotional materials. Instead, Ethicon supplies its representatives with a uniform set of materials developed by Ethicon for distribution. Moreover, Ethicon argues that all adverse events related to its mesh products are reported in adverse event reports, and those reports have previously been produced to Plaintiffs. Finally, Ethicon contends through the affidavit of its document vendor that to locate, collect, process, review, and produce 300 additional sales representative files would require the efforts of a team of professionals, working over a period of four to six months, at a cost of between \$500,000

and \$1,000,000.

Under Fed.Rule.Civ.P. 26(c), a party may move the court for an order precluding or limiting proposed discovery if necessary to protect the party from annoyance, embarrassment, oppression, undue burden or expense. The person or party moving for the protective order bears the burden of demonstrating good cause, *Minter v. Wells Fargo Bank, N.A.*, 258 F.R.D. 118, 124 (D.Md.2009), and in doing so, “may not rely upon ‘stereotyped and conclusory statements,’ but must present a ‘particular and specific demonstration of fact,’ as to why a protective order should issue.” *Baron Fin. Corp. v. Natanzon*, 240 F.R.D. 200, 202 (D.Md.2006) (*quoting* 8A Charles Alan Wright et al., *Fed. Prac. & Proc. Civ.* § 2035 (2d ed.1994)). The court has broad discretion under Fed.R.Civ.P. 26(c) “to decide when a protective order is appropriate and what degree of protection is required.” *Seattle Times v. Rhinehart*, 467 U.S. 20, 36, 104 S.Ct. 2199, 81 L.Ed.2d 17 (1984). In crafting a protective order, the court “may be as inventive as the necessities of a particular case require in order to achieve the benign purposes of the rule.” 8A Charles Alan Wright, Arthur R. Miller, & Richard L. Marcus, *Federal Practice and Procedure*, § 2036 (3d ed.).

Furthermore, under Fed.R.Civ.P 26(b)(2)(C), the court **must**, on motion or on its own:

limit the frequency or extent of discovery, otherwise allowed by these rules or by local rule if it determines that “(i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

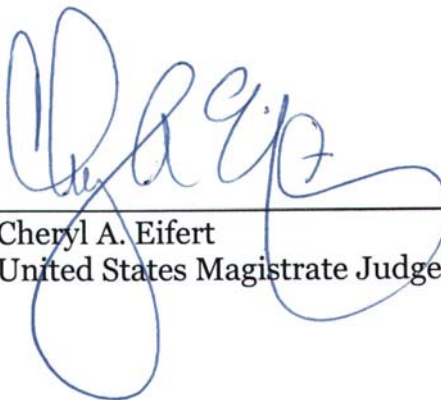
This rule “cautions that all permissible discovery must be measured against the yardstick of proportionality.” *Lynn v. Monarch Recovery Management, Inc.*, 285 F.R.D. 350, 355 (D. Md. 2012) (quoting *Victor Stanley, Inc. v. Creative Pipe, Inc.*, 269 F.R.D. 497, 523 (D. Md. 2010)). “The application of [Rule 26(b)(2)(C)] involves a highly discretionary determination based upon an assessment of a number of competing considerations.” *Sommerfield v. City of Chicago*, 613 F.Supp.2d 1004, 1017 (N.D.Ill.2009).

The undersigned finds that under the standards of both rules, good cause exists for denying Plaintiffs’ motion to compel. Starting with Plaintiffs’ first argument, their contention that the remaining sales representative files will reveal an otherwise undiscovered company policy is unpersuasive. Plaintiffs offer only speculation that Ethicon will disavow a damaging document by singling out the creator as a renegade representative. By all accounts, such a factual scenario has not occurred. Consequently, the court has no reason to believe that the remaining sales representatives’ documents are likely to uncover misrepresentations by Ethicon. Plaintiffs’ second argument is equally unavailing. Ethicon indicates that its marketing and promotional materials are developed on a high corporate level and are uniformly communicated. Thus, Plaintiffs’ statement that Ethicon’s sales representatives are “overselling” the products, if accurate, should be easy to establish by the documents already produced. Plaintiffs have received sales, marketing, safety, regulatory, and manufacturing materials on all of the products at issue. Certainly, these documents should constitute the most substantial evidence of Ethicon’s patterns and practice in the distribution of pelvic mesh. Compelling Ethicon to produce materials at great expense that are unlikely to contain new and significant information on its patterns and practices ignores the purpose of the proportionality rule. Plaintiffs’ last two arguments suffer from the same weakness. When balancing the likelihood that the remaining sales

representatives' files will contain significant and currently undiscovered information against the uncontested costs associated with producing the files, the factors weigh in favor of prohibiting the requested discovery.<sup>1</sup> However, this Order is not intended to alter PTO #41 as it applies to the production of sales representatives' files for cases included in the current, or a future, Discovery Pool.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2327, and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:13-cv-23759. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at <http://www.wvsc.uscourts.gov>.

**ENTERED:** September 26, 2013.



Cheryl A. Eifert  
United States Magistrate Judge

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<sup>1</sup> Plaintiffs also argue that the gaps found in the 129 sales representatives' files already produced is an additional reason for compelling production of the remaining files. However, Plaintiffs provide no support for the necessary presumption that the unproduced files are more complete than the first 129 files.